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Issue Brief

The Ethical Review of Health Care Quality Improvement Initiatives: Findings from the Field

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ABSTRACT: Questions have been raised about whether and how health care quality improvement (QI) initiatives ought to be reviewed to address possible ethical issues associated with them. These questions have focused primarily on whether some QI initiatives meet the regulatory criteria for human subject research and should therefore be regulated and reviewed as such. Based on surveys of health care system professionals conducting QI initiatives and hospital CEOs, the authors find that QI initiatives are routinely reviewed by a variety of internal mechanisms prior to implementation, although rarely through an institutional review board or another independent body charged specifically with ethical oversight of QI initiatives. Further research, the authors say, is needed to achieve a better understanding of how review mechanisms for QI initiatives are structured, including information on who reviews these activities, how they are reviewed, and whether such processes include an ethical assessment of the proposed QI initiative.

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OVERVIEW

Over the last two decades, quality improvement (QI) initiatives have burgeoned in hospitals and health care systems.[1] While enhancing the quality of health care is important and often required by accrediting organizations and others, the process of improvement can raise ethical issues. Perhaps not surprisingly, there has been occasional, yet intensive, professional and public scrutiny regarding the ethical oversight of QI initiatives.

For instance, in 2001, questions were raised about a project on end-stage renal disease funded by the Centers for Medicaid and Medicare Services (CMS). Although CMS considered it to be a QI initiative, the Office for Human Research Protection (OHRP) determined the project was human subject research and that it should have been reviewed as such by an IRB prior to its implementation.[2] In

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2007, an anonymous whistle-blower accused the leaders of a project funded by the Agency for Healthcare Research and Quality (AHRQ) to reduce life-threatening infections in intensive care units of not having received proper ethical review.[3] That project involved testing the effectiveness of a checklist for improving the safety of intravenous catheters across hospitals in Michigan. The primary questions raised related to ethics oversight were whether the project constituted research and needed to be reviewed by institutional review boards (IRBs) at all participating hospitals, and whether informed consent should have been obtained from all patients who were involved.[4]

As noted by many commentators, QI and patient safety can be stymied unless there is a coherent approach to the ethical oversight of QI initiatives. However, achieving this turns out to be surprisingly complicated.

In the early 1990s, questions began to be raised as to whether quality improvement initiatives ought to be considered human subject research and reviewed and regulated as such.[5] Since then, a number of proposals have suggested criteria by which QI initiatives might be distinguished from human subject research, assuming that the latter requires review by an IRB while the former does not.[6] Other proposals attempted to examine whether formal ethical oversight of these activities is needed by focusing on the risk to potential participants posed by such activities, or the ways in which such activities potentially veer from the interests of current patients.[7] The goals of these proposals were to: 1) address, among other things, QI practitioners' uncertainty as to whether their activities should be reviewed by IRBs; and 2) limit the volume of QI initiatives unnecessarily referred to IRBs already burdened with a heavy volume of human subject research (Exhibit 1).

While there is no consensus regarding the correct approach, there is an obvious need for oversight of at least some QI initiatives. In addition, many proposals rest upon the current system of ethical oversight of research, although others suggest the possibility of developing and using other approaches.

Despite myriad proposals regarding the ethical oversight of QI, there is surprisingly little empirical research that has reported on the review and oversight of QI initiatives. One group of investigators surveyed IRBs at academic medical centers to find out whether they had local guidelines regarding the review and regulation of QI initiatives.[8] They found that the variety of attributes used by IRBs to distinguish QI initiatives from human subject research mirrored those found in the literature. A second group of investigators surveyed IRB chairs and quality officers at hospitals with at least 400 beds; they also surveyed editors of peer-reviewed journals.[9] In response to a set of six vignettes about hypothetical projects, they found quality officers less likely than either IRB chairs or journal editors to respond that a project needed to be reviewed by an IRB, and found disagreement between quality officers and IRB chairs from the same institution.

In this issue brief, we describe our recent efforts to collect data to advance the policy debate.

EMPIRICAL DATA FROM HEALTH CARE PROFESSIONALS AND SYSTEMS

To inform the development of policy regarding the appropriate ethical oversight for QI research activities, we surveyed two groups: health care system professionals conducting QI initiatives, and the leadership of those organizations in which QI activities are conducted. Our first survey, conducted in collaboration with the Institute for Healthcare Improvement (IHI), was completed in April 2009.[10] The second survey was conducted in November and December of 2009 with CEO members of the American Hospital Association (AHA). Both surveys are described briefly in turn, followed by a comparison of the results. These studies begin to fill a gap in whether institutions have viewed their QI work as research and what types of ethical oversight such projects have received.

Survey of QI Practitioners

Our first survey was of quality improvement practitioners (QIPs) who had participated in the Institute for Healthcare Improvement's "100,000 Lives" Campaign, which recruited hospitals and health systems to adopt

Exhibit 1. Proposed Criteria

Criteria	Reference(s)
Characterization of benefits is contested	Lo and Groman 2003
Delayed or ineffective feedback of results to subjects of project	Lynn 2004; Baily, Bottrell, Jennings et al. 2006; Lynn et al. 2007
Engagement with/commitment to the local setting	Brett and Grodin 1991; Lynn 2004; Baily, Bottrell, Jennings et al. 2006; Lynn et al. 2007
Intent/goal of the initiator	Brett and Grodin 1991; Wagner 2003
Intent to publish	Koshcnitzke, McCracken and Pranulis 1992 (Note: Casarett, Karlawish and Sugarman 2000; Lo and Groman 2003 disagree that intent to publish ought to serve as criteria to distinguish quality improvement initiatives from human subject research.)
Majority of patients are **not** expected to benefit directly from the knowledge to be gained	Casarett, Karlawish and Sugarman 2000
Novelty of intervention	Brett and Grodin 1991; NBAC 2001; Lo and Groman 2003; Baily, Bottrell, Jennings et al. 2006; Lynn et al. 2007
Majority of patients are expected to benefit directly from the knowledge to be gained but they would be subjected to additional risks or burdens beyond usual clinical practice to make the results generalizable.	Casarett, Karlawish and Sugarman 2000
Patients to be exposed to more than minimal risk. For example, patients to receive less care that is considered standard.	Lo and Groman 2003; Goldman et al. 2010; Lynn 2004
Prospective design	Brett and Grodin 1991; Koshcnitzke, McCracken and Pranulis 1992; Bellin and Dubler 2001
Utilizes methods and techniques commonly used in research (e.g., randomization)	Wagner 2003; Lynn 2004; Baily, Bottrell, Jennings et al. 2006; Lynn et al. 2007
Substantial funding, funding from an outside organization	Lynn 2004; Baily, Bottrell, Jennings et al. 2006; Lynn et al. 2007
Substantial nontherapeutic aims; aims of project extend beyond the immediate interests of patients subject to the activity.	Lynn 2004; Grady 2007

patient-safety initiatives aimed at reducing medical harm.[11] The survey was sent to 500 QIPs, and 126 (25%) responded.

QI review mechanisms. The majority of IHI respondents in this study self-identified as managers either in a QI/safety department or other hospital department (n=63). Most respondents indicated that QI initiatives conducted by faculty and staff affiliated with their organization are subject to some type of review prior to implementation (83%); of those, most reported that the review is conducted most of the time or always (85%). The three most common mechanisms reported were review by: the QI management team/office; clinical leadership conducting QI; and an advisory board (or equivalent) created for the purpose of reviewing QI. Two-thirds of respondents indicated that the QI oversight mechanism in place at their institution identifies and considers ethical issues related to QI well or very well. A minority of respondents (20%) indicated that the national policy discussions about the oversight of QI affected ongoing or planned QI projects in which they were involved.

Ethical considerations. Respondents were given a set of considerations thought to be relevant to the ethical conduct of QI initiatives. They were asked to indicate: 1) whether each was relevant to the ethical conduct of QI initiatives at their institution; and 2) how important they believed each such consideration was for the ethical conduct of QI generally. Eighty-three percent and 82 percent of respondents, respectively, strongly

Exhibit 2. AHA Sample—Regional Diversity

Census Division/Region	Survey Sample (n=297)	Total AHA Sample (n=5,807)
Puerto Rico (0)	0 (0%)	60 (1%)
New England/Northeast (1)	17 (6%)	230 (4%)
Mid-Atlantic/Northeast (2)	27 (9%)	522 (14%)
East North Central/Midwest (3)	40 (14%)	833 (14%)
West North Central/Midwest (4)	57 (19%)	858 (15%)
South Atlantic/South (5)	20 (7%)	497 (9%)
East South Central/South (6)	53 (18%)	743 (12%)
West South Central/South (7)	40 (13%)	1,023 (18%)
Mountain/West (8)	20 (7%)	440 (8%)
Pacific/West (9)	23 (7%)	601 (10%)

agreed that minimal risk to patients and privacy and confidentiality are guiding principles for QI initiatives conducted at their institution and to QI more generally. A majority of respondents also agreed that assessing established practices (67%), scientifically sound design (62%), transparency (62%), and the identification and minimization of potential conflicts (57%) are ethical considerations for QI initiatives conducted at their institution.

Survey of Hospital CEOs

Our second survey, conducted in collaboration with the American Hospital Association, was designed to get perspective on the results from the previous survey of CEOs at U.S. hospitals and health systems. The survey was limited to five questions, and we asked the most informative items from the first survey. The methods used for the AHA survey were similar to those used in the first survey.

The survey was sent to 5,807 potential respondents by e-mail or fax (depending on the respondents' previously stated preference) on November 30, 2009. A notice about the survey distribution and request for completion was posted in the weekly newsletter sent to AHA members. Eligible respondents were sent a reminder and a second request for completion was posted in the AHA newsletter. We also abstracted demographic data regarding hospitals and health systems represented in the AHA database including region, teaching hospital or not, and number of hospital

Exhibit 3. AHA Sample—Number of Beds

Number of Beds	Survey Sample (n=297)	Total AHA Sample (n=5,807)
1–24	29 (10%)	609 (10%)
25–49	63 (21%)	1,347 (23%)
50–99	65 (22%)	1,196 (21%)
100–199	50 (17%)	1,201 (21%)
200–299	34 (11%)	628 (11%)
300–399	23 (7%)	367 (6%)
400–499	11 (4%)	187 (3%)
500+	22 (7%)	272 (5%)

Exhibit 4. AHA Survey—Frequency of QI Review

Frequency of QI Review	Number	Percentage
Always	211	71%
Sometimes	77	26%
Seldom	7	2%
Never	0	0%
Don't know	2	1%
Total	297	100%

beds. The statistical analysis was descriptive, using means and medians as appropriate. To identify associations between survey questions and demographic data, we used logistic regression models. A total of 297 respondents completed the survey (response rate=5%). (No trends were found that indicated that our sample AHA respondents diverged substantively from the AHA population; see Exhibits 2 and 3.)

Frequency of review. Seventy-one percent of AHA CEO respondents indicated that QI initiatives conducted by faculty and staff affiliated with their organization always are reviewed by some entity within their organization prior to implementation, while 26 percent stated that QI initiatives sometimes were reviewed prior to implementation (Exhibit 4).

Type of oversight mechanism. Only one-quarter (23%) of AHA CEO respondents indicated that initiatives were routinely submitted to their IRB. No statistical relationship was found between the AHA respondent's stated affiliation with a teaching hospital and a report of routinely submitting QI initiatives to an IRB (Exhibit 5).

Source of funding for QI efforts. When asked how QI initiatives were funded at their institution, AHA CEOs most commonly cited internal organizational funding. A statistically significant relationship was found between the respondent's relationship to a teaching hospital and the receipt of federal funding to conduct QI initiatives (p=.02) (Exhibit 6).

Exhibit 5. AHA Survey—Type of Oversight Mechanism

Mechanism	Yes	No	Don't Know
Advisory/managerial board (or equivalent) not created specifically for the purpose of reviewing QI initiatives	156 (57%)	115 (42%)	3 (1%)
Advisory/managerial board (or equivalent) created specifically for the purpose of reviewing QI initiatives	176 (64%)	99 (36%)	2 (1%)
QI management team/office	268 (93%)	21 (7%)	0 (0%)
Oversight by a standing clinical/medical leadership team	226 (81%)	53 (19%)	0 (0%)
Clinical leaders conducting QI initiatives	240 (86%)	36 (13%)	3 (1%)
Local institutional policy specific to QI initiatives	140 (53%)	111 (42%)	12 (5%)
Routine submission of QI initiatives to an IRB	58 (23%)	179 (72%)	13 (5%)

Note: Respondents marked all that were applicable.

Exhibit 6. AHA Survey—Funding Source for QI Initiatives

Funding Source	Number/(Percentage) Reporting Yes
Internal organizational funding	190 (70%)
State funding	66 (24%)
Foundation grant	52 (19%)
Federal funding	45 (15%)
Pharmaceutical industry	8 (3%)
Other private industry funding	10 (4%)
None	6 (2%)
Other	11 (4%)

Consideration of ethical issues. More than three-quarters of AHA CEO respondents indicated that the oversight mechanism in place at their institution does "well" (56%) or "very well" (26%) identifying and considering ethical issues related to the QI initiatives submitted for review. No statistically significant relationship was found between respondents reporting how well the oversight mechanism reviews the ethical issues related to their QI initiative with routine submission to an IRB (Exhibit 7).

Guiding ethical considerations for QI. The majority of AHA CEO respondents ranked minimal risk to patients/health care providers/systems, assessing established practices (initiating a practice seen to be safe and effective in other settings, or combining changes in practice all found to be safe and effective but not previously adopted as a package), and attention to privacy and confidentiality (upholding professional standards and HIPAA compliance) as the ethical considerations that ought to guide the QI initiatives conducted at their institutions (Exhibit 8).

Comparing the Results

Given such a low response rate to the survey of AHA CEOs, we believe the results from the IHI QIP survey are more reliable. However, the results of the AHA survey seem to corroborate the findings from the IHI survey. Following are some noteworthy comparisons among the results:

- Compared with the IHI QIPs surveyed, many more AHA CEOs reported that QI initiatives are always reviewed (70%). Of the IHI QIP respondents who indicated QI initiatives are subject to review, 33 percent reported that a review is always conducted and 50 percent that a review is conducted sometimes.
- A similar minority of IHI QIP and AHA CEO respondents reported sending QI initiatives to an IRB for review.
- Nearly twice as many AHA CEOs as IHI QIPs indicated that QI initiatives at their institution are funded by internal sources (IHI=40%; AHA=70%).
- A larger proportion of AHA CEO respondents reported that the oversight mechanism pays attention to ethical issues "well" (IHI=45%; AHA=56%).
- Comparing the AHA CEO respondent ranking and the IHI QIP respondent ranking of the top four ethical considerations that ought to guide the QI initiatives conducted at their institutions, the only difference was that AHA CEO respondents ranked assessing established practices second on their list, while IHI QIP respondents ranked it third.

Exhibit 7. AHA Survey—Consideration of Ethical Issues

Consideration of Ethical Issues	Number	Percentage
Very well	76	26%
Well	166	56%
Not well	32	11%
Don't know	23	8%
Total	297	100%

DISCUSSION

According to our data, quality improvement initiatives are routinely reviewed by a variety of internal mechanisms prior to implementation, although rarely through the institutional review board or any other independent body charged specifically with ethical oversight. In fact, only a few respondents indicated that they submit QI initiatives to an IRB. While questions have been raised about the independence of IRBs, one could argue that the IRB could provide a more independent assessment of QI initiatives than could offices and individuals who are administratively responsible for QI efforts or otherwise closely connected with them.[12] However, this concern begs the question of whether the IRB is properly constructed to conduct reviews of QI. As argued by Perneger, a central issue seems to be independent ethical review.[13] Also relevant is whether activities which pose little if any risks or burdens even require such a review.

Toward Best Practices for QI Ethical Review

Further research is needed for a better understanding of how existing review mechanisms for QI initiatives are structured, including who reviews these activities, how they are reviewed, and whether such processes include an ethical assessment of the proposed QI intervention. Simply put, whether and to what extent the review attends to the ethics of the initiative remains unknown. Little is known also about the training, skills, or process used for the non-IRB reviews, although there is likelihood of wide variation. And little is known about how IRBs approach QI initiatives, the consequent modifications of QI activities (such as a change in design or requiring informed consent), and the implications of reviewing QI on IRBs.

With further investigation, sound practices with regard to the ethical review of QI initiatives might well be identified. Such research could identify important insights that could lead to the development of best practices, including the relative importance of

Exhibit 8. AHA Survey—Ethical Considerations

	RANKING			
Consideration	1	2	3	Total
Minimal risk to patients	140	43	22	205 (70%)
Assessing established practices	52	56	62	170 (57%)
Privacy and confidentiality	39	74	52	165 (55%)
Transparency	16	42	54	113 (38%)
Balancing	16	24	28	69 (23%)
Scientifically sound design	16	27	23	67 (23%)
Commitment to shared learning	5	17	31	54 (19%)
Identification and minimization of conflicts of interest	1	2	13	17 (6%)

the ethical issues identified by both the IHI and AHA respondents as those most relevant to the conduct of QI.

The respondents to our surveys agree that the ethical considerations most relevant to the conduct of QI are: exposing those subjected to the QI initiative (i.e., patients, health care providers, systems) to no more than minimal risk, the assessment of established practices, and respect for the privacy and confidentiality of those subject to the QI initiative. While these data are important, attitudes about ethical issues are not normative, and a robust moral framework for the systematic integration of QI research and practice with health care delivery is needed.

The key question going forward is not how to distinguish QI from research; advances in QI require the conduct of QI research. Rather, the challenge rests in constructing a system that provides incentives for the development, evaluation, dissemination, and implementation of effective interventions to improve the quality and safety of medical care (ends shared by all participants in the health care system), while at the same time providing appropriate safeguards for patients and clinicians affected by the activities—whether deemed research or not.

In conclusion, the characteristics of QI initiatives deemed to require IRB review have evolved over time, yet there is still a lack of consensus on this issue. Similarly, there remains little consensus regarding the characteristics that distinguish QI initiatives from human subjects research. Pursuing such paths may ultimately not prove to be the most useful approach to determine the appropriate mechanism, or mechanisms, for the ethical oversight of QI. Our research suggests that the review of QI initiatives varies widely among hospitals, though most are not reviewed by an IRB. Further research is needed to understand barriers to the review of QI, the efficacy of alternative approaches to review, and the development and dissemination of best practices regarding review of QI studies. This research is essential to ensuring that we continue to improve quality of care and protect patients' rights and interests.

Notes

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